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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,622	03/18/2004	John McCafferty	05569.0004.DVUS11	6206

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HOWREY SIMON ARNOLD & WHITE, LLP
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Washington, DC 20004-2402

EXAMINER

STEELE, AMBER D

ART UNIT	PAPER NUMBER
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1639

MAIL DATE	DELIVERY MODE
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07/03/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/803,622

Applicant(s)

MCCAFFERTY ET AL.

Examiner

Amber D. Steele

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on April 2, 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 1-8 and 10-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9 and 13-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on March 18, 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 09/726,219.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Status of the Claims

1. The amendment to the claims received on August 8, 2007 amended claim 9.
The new claim listing provided on April 2, 2008 changed the status identifiers only.
Claims 1-17 are currently pending.
Claims 9 and 13-17 are currently under consideration.

Election/Restrictions

2. Claims 1-8 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim.
Election was made **without** traverse in the reply filed on April 27, 2006.
3. Claims 10-12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on April 27, 2006.

Priority

4. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d) of United Kingdom application 9015198.6 7/10/1990; United Kingdom application 9022845.3 10/19/1990; United Kingdom application 9024503.6 11/12/1990; United Kingdom application 9104744.9 3/6/1991; United Kingdom application 9110549.4 5/15/1991.
The certified copies have been filed in parent Application No. 09/726,219, filed on November 28, 2000.

5. The present application claims status as a DIV of 09/726,219 11/28/2000 PAT 6,806,079 which is a CON of 08/484,893 06/07/1995 PAT 6,172,197 which is a CON of 07/971,857 01/08/1993 PAT 5,969,108 which is a National Stage application filed under 35 U.S.C. § 371 of PCT/GB91/01134 07/10/1991.

6. Please note: the current Bib Data Sheet (see PAIR) does not indicate that 07/971,857 is a 35 U.S.C. § 371 of PCT/GB91/01134. The examiner of record has attempted on several occasions to correct the Bib Data Sheet. However, since 07/971,857 is not associated with PCT/GB91/01134 in the USPTO records, the Bib Data Sheet could not be changed. Applicants are requested to inquire about a Bib Data Sheet change.

Invention as Claimed

7. A method for producing a binding molecule specific for a particular target epitope or antigen, which method comprises the steps of: producing a population of filamentous bacteriophage particles displaying at their surface a population of binding molecules wherein each binding molecule in the population of binding molecules has a binding domain and the population of binding molecules has a range of binding specificities wherein the binding domain of the binding molecules consists of an antibody heavy chain variable domain and wherein each filamentous bacteriophage particle contains nucleic acid with a nucleotide sequence encoding the binding molecule expressed from the nucleic acid and displayed by the particle at its surface and selecting for a filamentous bacteriophage particle displaying a binding molecule with a desired specificity by contacting the population of filamentous bacteriophage particles with a target

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epitope or antigen so that individual binding molecules displayed on filamentous bacteriophage particles with the desired specificity bind to said target epitope or antigen and variations thereof.

Please note: an antibody heavy chain variable domain includes the following structures: FW1-CDR1-FW2-CDR2-FW3-CDR3-FW4; CDR1; CDR2; CDR3; etc. (i.e. any structure comprising an antibody variable domain).

Withdrawn Rejections

8. The rejection of claims 9 and 13-17 under 35 U.S.C. 102(e) as being anticipated by Dower et al. U.S. Patent 5,427,908 filed May 1, 1990 is withdrawn in view of applicants persuasive arguments.

9. Claims 9 and 13-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ladner et al. WO 90/02809 published March 22, 1990 and Sastry et al. PNAS 86: 5728-5732, 1989 (provided by applicants in the IDS).

New Rejections

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 9 and 13-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dower et al. U.S. Patent 5,427,908 filed May 1, 1990 and Taub et al. JBC 264(1): 259-265, 1989.

For present claim 9, Dower et al. teach methods of producing filamentous bacteriophage surface expressing binding domains of antibody fragments including VH that are encoded by nucleic acid sequences and screening the libraries of filamentous bacteriophage including fd, fl, and M13 expressing the VH and/or VL against various antigens, antigenetic determinants, or haptens in order to select a specific binding domain (please refer to the entire specification particularly the abstract; columns 1-12; Example I).

For present claim 13, Dower et al. teach isolating the nucleic acid encoding the antibody fragments from spleen (i.e. peripheral lymphoid tissue, peripheral blood lymphocytes, B-lymphocytes; please refer to column 4 and Example I).

For present claim 14, Dower et al. teach bacteriophage vectors (i.e. phagemid; please refer to the entire specification particularly the abstract; column 1, lines 60-67; column 2, lines 15-43; Example I).

For present claim 15, Dower et al. teach that the nonbound antibodies are washed away and the bound phage can be eluted from the antigen or hapten (please refer to column 10, lines 62-67; column 11, column 12, lines 1-23).

For present claim 16, Dower et al. teach that the previously antigen or hapten bound phage are recovered (please refer to column 11, lines 60-67; column 12, lines 1-31).

For present claim 17, Dower et al. teach recloning DNA from the eluted and recovered previously antigen or hapten bound phage particles via expression in a suitable eukaryotic or

prokaryotic expression vector for production of large amounts of the binding domain protein (please refer to column 12, lines 32-41).

However, the main focus of Dower et al. is screening for VH and VL combinations.

For present claim 9, Taub et al. teach screening for binding of heavy chain CDR domains particularly CDR3 including competitive binding assays (please refer to the entire reference particularly the abstract; pages 261, right column; page 262-264; Figures 3-6).

The claim would have been obvious because the substitution of one known element (phage-displayed VH-VL as taught by Dower et al.) for another (i.e. CDR alone as taught by Taub et al.) would have yielded predictable results (i.e. binding to epitopes/antigens) to one of ordinary skill in the art at the time of the invention. In addition, the claims would have been obvious because a particular known technique (i.e. phage display of polypeptides for screening assays as taught by Dower et al.) was recognized as part of the ordinary capabilities of one skilled in the art. See *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007).

12. Claims 9 and 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ladner et al. WO 90/02809 published March 22, 1990 and Weir et al. J. Biochem. 100: 69-72, 1966.

For present claims 9 and 14-17, Ladner et al. teach methods of surface displaying binding domains on filamentous bacteriophage particles wherein the binding domains (i.e. scFv comprising VH and VL) are encoded by nucleic acid sequences and then screened via binding to targets (please refer to abstract; pages 8-14; pages 17-18; pages 42-48). In addition, Ladner et al. teach bacteriophage vectors (i.e. phagemids), separation of unbound phage, separation of phage

form antigen, recovery of phage, and producing additional phage display libraries (please refer to the entire specification particularly pages 8, 11-15, 18, 42-45).

However, while Ladner et al. (WO 90/02809) discuss the expression of scFv on the surface of filamentous phage, the expression of VH only is not taught.

For present claim 9, Weir et al. teach antigen binding assays for VH alone (please refer to the entire reference particularly the abstract; Tables 1-2; page 70, right column).

The claim would have been obvious because the substitution of one known element (phage-displayed VH-VL as taught by Ladner et al.) for another (i.e. VH alone) would have yielded predictable results (i.e. binding to epitopes/antigens) to one of ordinary skill in the art at the time of the invention. In addition, the claims would have been obvious because a particular known technique (i.e. phage display of polypeptides for screening assays as taught by Ladner et al.) was recognized as part of the ordinary capabilities of one skilled in the art. See *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007).

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Williams et al. PNAS 86: 5537-5541, 1989.

Future Communications

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amber D. Steele whose telephone number is 571-272-5538. The examiner can normally be reached on Monday through Friday 9:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Amber D. Steele/
Patent Examiner, Art Unit 1639

June 24, 2008